

activities, confidence limits are determined where possible for group dose calculations. The uncertainty analysis quantifies the errors in available data or in the model used in the absence of data. Confidence limits are based on the uncertainty of all relevant input parameters, and thus vary with the quality of the input data. They also consider the possible range of doses due to the size of the exposure group being examined. Typical sources of error include orientation of the weapons, specific weapon yields, instrument error, fallout intensity data, time(s) at which data were obtained, fallout decay rate, route of personnel movements, and arrival/stay times for specific activities.

(f) *Comparison with film badge records.*

(1) Calculations of gamma dose were compared with film badge records for two military units at Operation PLUMBBOB to initially validate this methodology. Where all parameters relating to radiation exposure were identified, direct comparison of gamma dose calculations with actual film badge readings was possible. Resultant correlations provided high confidence in the methodology.

(2) Film badge data may, in some cases, be unrepresentative of the total exposure of a given individual or group; nevertheless, they are extremely useful for direct comparison of incremental doses for specific periods, e.g., validating the calculations for the remaining, unbadged period of exposure. Moreover, a wide distribution of film badge data often leads to more definitive personnel grouping for dose calculations and to further investigation of the reason(s) for such distribution. In all cases, personnel film badge data are not used in the dose calculations, but rather are used solely for comparison with and validation of the calculations. For dose reconstructions accomplished to date, comparison has been favorable and within the confidence limits of the calculations.

**§218.4 Dose estimate reporting standards.**

The following minimum standards for reporting dose estimates shall be uniformly applied by the Military Services when preparing information in response to an inquiry by the Veterans

Administration, in connection with a claim for compensation, or by a veteran or his or her representative. The information shall include all material aspects of the radiation environment to which the veteran was exposed and shall include inhaled, ingested, and neutron doses, when applicable. In determining the veteran's dose, initial neutron, initial gamma, residual gamma, and internal (inhaled and ingested) alpha, beta, and gamma shall be considered. However, doses will be reported as gamma dose, neutron dose, and internal dose. To the extent to which the information is available, the responses will address the following questions:

(a) Can it be documented that the veteran was a test participant? If so, what tests did he attend and what were the specifics of these tests (date, time, yield (unless classified) type, location and other relevant details)?

(b) What unit was the man in? What were the mission and activities of the units at the test?

(c) To the extent to which the available records indicate, what were his duties at the test?

(d) Can you corroborate the specific information relevant to the potential exposure provided by the claimant to the Veterans Administration and forwarded to the Department of Defense? What is the impact of these specific activities on the claimant's reconstructed dose?

(e) Is there any recorded radiation exposure for the individual? Does this recorded exposure cover the full period of test participation? What are the uncertainties associated with the recorded film badge dose?

(f) If recorded dosimetry data is unavailable or incomplete, what is the dose reconstruction for the most probable dose, with error limits, if available?

(g) Is there evidence of a neutron or internal exposure? What is the reconstruction?

Upon request, the participant or his or her authorized representative will be informed of the specific methodologies and assumptions employed in estimating his or her dose.

## PART 219—PROTECTION OF HUMAN SUBJECTS

### Sec.

- 219.101 To what does this policy apply?
- 219.102 Definitions.
- 219.103 Assuring compliance with this policy—research conducted or supported by any Federal Department or Agency.
- 219.104–219.106 [Reserved]
- 219.107 IRB membership.
- 219.108 IRB functions and operations.
- 219.109 IRB review of research.
- 219.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.
- 219.111 Criteria for IRB approval of research.
- 219.112 Review by institution.
- 219.113 Suspension or termination of IRB approval of research.
- 219.114 Cooperative research.
- 219.115 IRB records.
- 219.116 General requirements for informed consent.
- 219.117 Documentation of informed consent.
- 219.118 Applications and proposals lacking definite plans for involvement of human subjects.
- 219.119 Research undertaken without the intention of involving human subjects.
- 219.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal Department or Agency.
- 219.121 [Reserved]
- 219.122 Use of Federal funds.
- 219.123 Early termination of research support: Evaluation of applications and proposals.
- 219.124 Conditions.

AUTHORITY: 5 U.S.C. 301; 42 U.S.C. 300v–1(b).

SOURCE: 56 FR 28012, 28021, June 18, 1991, unless otherwise noted.

### **§ 219.101 To what does this policy apply?**

(a) Except as provided in paragraph (b) of this section, this policy applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency which takes appropriate administrative action to make the policy applicable to such research. This includes research conducted by federal civilian employees or military personnel, except that each department or agency head may adopt such procedural modifications as may be appropriate from an administrative standpoint. It also includes research con-

ducted, supported, or otherwise subject to regulation by the federal government outside the United States.

(1) Research that is conducted or supported by a federal department or agency, whether or not it is regulated as defined in § 219.102(e), must comply with all sections of this policy.

(2) Research that is neither conducted nor supported by a federal department or agency but is subject to regulation as defined in § 219.102(e) must be reviewed and approved, in compliance with § 219.101, § 219.102, and § 219.107 through § 219.117 of this policy, by an institutional review board (IRB) that operates in accordance with the pertinent requirements of this policy.

(b) Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

(i) Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and

(ii) Any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:

(i) The human subjects are elected or appointed public officials or candidates for public office; or